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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/392,728	09/09/1999	KLAUS STOCKEMANN	SCH-1550-C1	1685

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EXAMINER

NGUYEN, HELEN

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 05/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/392,728

Applicant(s)

STOCKEMANN ET AL.

Examiner

Helen Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-46, 48 and 50 is/are pending in the application.
- 4a) Of the above claim(s) 13, 14, 27, 28 and 33-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 15-26, 29-32, 48 and 50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The amendment of paper no. 12, filed November 11, 2002, is acknowledged. All arguments are fully considered.

Claims 47 and 49 are canceled.

Claim 50 is newly added.

Claims 13, 14, 27, 28, and 33-46 are non-elected.

Claims 1-12, 15-26, 29-32, 48 and 50 are presented for examination.

The elected species are: A/  $11\beta$ -(4-acetylphenyl)- $17\beta$ -hydroxy- $17\alpha$ -(1-propenyl)estra-4, 9-dien-3-one. B/ Drospirenone (dihydrospirorenone).

❖ The Examiner carefully reviewed the amendment of paper no. 12, filed March 11, 2002. The claim objection and rejections of record set forth in the previous rejection, paper no. 9, under 35 U.S.C. 112, first paragraph, 35 U.S.C. 102 (a), and 103(a) stand for reasons as follows:

#### ***Claim objection***

In an effort to overcome the objection to claim 47 being a duplicate of claim 31, Applicants cancel claim 47 and introduce claim 50. However, claim 50 is also a duplicate of claim 31. Therefore, the objection remains, now directed to claim 50.

Claim 50 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 31. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). *Therefore, claim 50 has not been further examined.*

***Claim rejection- 35 USC § 112***

The following is a quotation of the **first paragraph of 35 U.S.C. 112**:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- ❖ Claims 1-12, 15-26, 29-32, 48 and 50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant discloses an amount effective to inhibit ovulation on page 9, lines 22-24 of 2 mg for RU486 and 0.01-30mg for other progesterone antagonists. However, these amounts

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overlap the ranges disclosed in column 5, lines 15-22 of US Patent 6,225,297 for non-ovulation inhibiting amounts. There appears to be a contradiction because the disclosed amounts effective to inhibit ovulation overlap those ranges disclosed in '297 for non-ovulation.

- Applicants argue that ovulation-inhibiting dosages are obtainable by testing. However, Applicants are silent as to the disclosure on page 9, lines 22-24 of the instant specification ovulation inhibiting amounts, which overlap the non-inhibiting ranges disclosed in US Patent No. 6,225,297.

***Claim rejection- 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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- ❖ Claims 1-12, 15-26 are rejected under 35 U.S.C. 102(a) as being anticipated by Stockemann et al., DE 4344463A1 ('463) (see IDS of Feb. 09, 2000).

Claims 1-12, 15-26 are not novel over the prior art ('463). See page 2, lines 61 to 68, page 3, lines 42 to 44, page 4, lines 1 to 19, page 5, lines 1 to 10, page 6, examples 1 to 3, claims 1, 3, 5, 6, 8, 9, 11 and 12.

- Applicants argue that DE 4344463A1 (DE '463) does not teach delivery of the ingredients in phases. However, such delivery is merely is an intended use. The intended use is not considered a patentable limitation during prosecution of a composition claim before the USPTO.

### ***Claim rejection- 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12, 15-26, 29-32, 48 and 50 are rejected under **35**

**U.S.C. 103(a)** as being unpatentable over Stockemann et al., DE 4344463A1 (DE '463) (see IDS of Feb. 09, 2000).

DE '463 is discussed above.

It would have been obvious to use a combination of competitive progesterone antagonist and gestagen as a contraceptive in view of DE '463.

As to the claimed kits, such are well known in the art.

- Applicants argue no motivation to combine. However, motivation has been provided. That is one of ordinary skill, even the layman, is cognizant of the convenience of contraceptive compositions provided in kit form and the fact that such kits are commercially available. Thus, it would be an obvious expedient to make the invention of DE '463 in kit form.

### ***Conclusion***

Claims 1-12, 15-26, 29-32, 48, and 50 are rejected.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes

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that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Applicant's amendment necessitated the new ground(s) of objection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory



period for reply expire later than SIX MONTHS from the date of this final action.

- ❖ This application contains claims 13, 14, 27, 28, and 33-46 are drawn to an invention nonelected with traverse in Paper No. 5, filed October 16, 2000. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is (703) 605-1198. The examiner can normally be reached on M-F (9:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary, Edward J. Webman can be reached at (703) 308-4432 or her supervisor, Minna Moezie can be reached at (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 305-3592 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Helen Nguyen  
Patent Examiner

May 23, 2002

EDWARD J. WEBMAN  
PRIMARY EXAMINER  
GROUP 1500